*Cobb County, Georgia v. Purdue Pharma, et al.*

*Case No: 1:18-op-45817-DAP*

# Expert Report of Lucas G. Hill, PharmD, FCCP

*June 23, 2024*

*Cobb County, Georgia v. Purdue Pharma, et al.*

*Case No: 1:18-op-45817-DAP*

**Expert Report of Lucas G. Hill, PharmD, FCCP**

*June 23, 2024*

**Table of Contents**

**A. Qualifications & Renumeration**

I earned my Doctor of Pharmacy (PharmD) degree from the University of Missouri–Kansas City School of Pharmacy. I then completed a two-year post-graduate residency at the University of Pittsburgh Medical Center Department of Family Medicine and a concurrent faculty development fellowship at the University of Pittsburgh School of Medicine. I am now a clinical associate professor at The University of Texas at Austin (UT) College of Pharmacy and director of the Pharmacy Addictions Research & Medicine (PhARM) Program. I have professional experience in community pharmacy, hospital pharmacy, inpatient acute care, and outpatient primary care.

Since 2017, I have served as principal investigator for over $42 million in funding from the U.S. Substance Abuse and Mental Health Services Administration, the Texas Health and Human Services Commission, and the City of Austin. This funding has supported a variety of efforts to reduce opioid-related morbidity and mortality, including development of the Texas Opioid Training Initiative (TXOTI). TXOTI has provided 54,676 hours of free continuing education to health professionals through a combination of online and in-person programs. I also serve as co-chair of the Texas Substance Use Symposium, an annual convening of health professionals, state agency staff, academics, and other key stakeholders seeking to address substance use and addiction in Texas.

I have authored 50 peer-reviewed journal articles and book chapters, including opioid-related research and commentaries in prestigious medical and pharmaceutical journals. I have delivered 96 presentations for prominent national organizations, including the Centers for Disease Control and Prevention, Office of National Drug Control Policy, National Institute on Drug Abuse, American Society of Addiction Medicine, and American Pharmacists Association. I am a past chair of the American Association of Colleges of Pharmacy Substance Use Disorder Special Interest Group, and I recently served on the Special Committee on Substance Use and Pharmacy Education which issued updated guidance for PharmD curricula in this domain. In 2020, I co-authored a joint statement from two practice and research networks of the American College of Clinical Pharmacy describing pharmacists' role in addressing the opioid crisis. In 2022, I co-chaired a National Institute on Drug Abuse Center for Clinical Trials Network workshop on pharmacy collaboration to treat opioid use disorder, and I was a panelist for a Substance Abuse and Mental Health Services policy priority meeting to explore the problem of limited buprenorphine availability in pharmacies. In 2024, I was a panelist for a national partner convening of the Centers for Disease Control and Prevention Opioid Rapid Response Program.

I provide instruction in the Pharmacotherapeutics of Pain and Addiction course in the UT College of Pharmacy, and I am the lead instructor for an interprofessional module on addiction that is delivered to students from medicine, nursing, pharmacy, and social work. I was awarded the 2020 American Pharmacists Association Generation Rx Award of Excellence and the 2021 American College of Clinical Pharmacy New Educator Award in recognition of

outstanding contributions to addiction-related education for pharmacists and other health professionals.

I am providing expert testimony on the standard of care for pharmacists. My professional billing rate is $2,000/day for testimony and $250/hour for non-testimony. My fees for preparing this report and testifying in this case are not contingent on the outcome of the proceedings or on the opinions presented herein. During the prior four years, I have provided testimony as an expert at trial or deposition in the following cases:

- Case No: D-101-CV-2017-02541, State of New Mexico, ex rel, Hector Balderas, Attorney General v Purdue Pharma, L.P., on behalf of defendants Kroger and Albertsons.
- Case No: 1:18-op-46326-DAP, Montgomery County Board of County Commissioners, et al. v. Cardinal Health, Inc., et al., on behalf of defendant Kroger.
- Case No: 19-C-9000, State of West Virginia v. The Kroger Co., et al., Civil Action No. 22-C-111 PNM, on behalf of defendant Kroger.

**B. Summary of Opinions**

- The gradual increase in opioid prescribing that began around 2000 and spread nationwide was the natural result of an extensively documented change in medical practice that was endorsed and promoted by leading medical experts, healthcare organizations, and governmental institutions.
- Community pharmacists do not have access to patients' medical records and thus have limited insight with which to evaluate the appropriateness of prescribed medications. For this reason, they must generally focus on identifying potential drug interactions, egregious prescribing errors, and other obvious safety concerns.
- Prescription monitoring programs, risk stratification algorithms, and dispensing "red flags" are imprecise tools with high false positive rates. This means that many patients identified as potentially high risk for diversion or drug-related harm by these tools will not experience drug-related harm.
- Delaying dispensing of an opioid prescription, or declining to dispense an opioid prescription altogether, can result in serious patient harm including but not limited to worsening of physical pain, induction of opioid withdrawal, increased risk for suicide, and increased risk for opioid-related overdose death.
- A pharmacist must be entrusted to use their professional judgment when weighing the risks and benefits of dispensing a prescribed controlled substance based on patient-specific factors. Inflexible standards of care that dictate a pharmacist's actions are inappropriate and have been specifically warned against by the U.S. Centers for Disease Control and Prevention in their revised 2022 opioid prescribing guideline.
- Only a licensed pharmacist may engage in pharmacy practice. Evaluation of a prescription's legitimacy and appropriateness is an element of pharmacy practice that requires a licensed pharmacist to exercise professional judgment that incorporates their nuanced understanding of a specific patient and community context. Pharmacy corporations are not licensed to engage in pharmacy practice and should generally not interfere with a licensed pharmacist's exercise of their professional judgment.

**C. The Triple Wave Opioid Crisis**

In 2000, the Joint Commission on Accreditation of Healthcare Organizations issued new pain management standards that emphasized the need for more consistent assessment and treatment of physical pain.[1] These standards reflected the input of leading experts and organizations in medicine, and these standards were consistent with previously issued guidance from the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the American Pain Society. Issuance of these standards coincided with a profound shift in the practice of medicine as it related to the treatment of physical pain. From 1999–2010, prescribing of opioid analgesics quadrupled in the United States.[2] Unfortunately, during this same timeframe, the rate of overdose deaths related to opioid analgesics also increased substantially.[3] This period of persistently increasing opioid prescribing has since become known as the first wave of the opioid crisis. In retrospect, experts generally agree that opioid prescribing was excessive during this timeframe, though it is clear this high rate of prescribing was encouraged by medical and governmental agencies based on the prevailing views of pain management experts and with the goal of optimizing compassionate care for people suffering from acute and chronic physical pain.

The second wave of the opioid crisis is generally defined as occurring from 2010–2015.[3] During this timeframe, overdose deaths due to opioid analgesics remained relatively stable even though opioid prescribing was decreasing steadily each year. Meanwhile, overdose deaths related to heroin quadrupled. This shift in deaths has been described by some as an unintended consequence of supply reduction strategies, as well as the drastic increase in availability and decrease in pricing of heroin. Key supply reduction strategies applied to the opioid crisis include reduced prescribing of opioid analgesics and implementation of prescription monitoring programs.

The third wave of the opioid crisis is marked by the proliferation of potent synthetic opioids in the illegal drug supply, first as adulterants to heroin and later as replacements for it. While these potent synthetic opioids are sometimes referred to as “fentanyls” or “illegally-manufactured fentanyls”, they are actually a large and growing group of molecules that share the following characteristics: (1) they do not require opium poppies for production and thus offer a competitive benefit to illegal drug distributors, (2) they are more potent than heroin and can thus be transported more easily while avoiding detection by law enforcement agencies, and (3) they are not manufactured by pharmaceutical companies, prescribed by medical professionals, or dispensed from pharmacies.[4,5] From 2013–2017, overdose deaths related to these potent synthetic opioids increased nearly ten-fold, and they now account for a substantial majority of all drug-related overdose deaths.[6] This transition from opioid analgesics to heroin and ultimately to potent synthetic opioids has been described as the latest in a long series of examples demonstrating the unintended consequences of supply reduction strategies applied to drugs.[7]

When considering the triple wave opioid crisis and the unintended consequences of supply reduction strategies, it is notable that the U.S. Centers for Disease Control and Prevention (CDC) did not issue their landmark guideline for prescribing opioids for chronic pain until 2016.[8] The 2016 guideline was a collection of 12 recommendations intended to reduce inappropriate prescribing of opioid analgesics. Eleven of the recommendations were based on low quality evidence, and the twelfth recommendation focused on offering proven medications for opioid use disorder to patients qualifying for that diagnosis. In 2019, the authors of the 2016 guideline published a clarification due to concern that it was being misapplied by numerous federal and state agencies, as well as insurers and healthcare institutions, resulting in harm to patients.[9] Patients already maintained on relatively high doses of opioids were a population of particular concern to the 2016 guideline authors, as demonstrated by this passage in their 2019 clarification:

> "…the [2016 guideline] states that 'Clinicians should…avoid increasing dosage to ≥90 MME [morphine milligram equivalents]/day or carefully justify a decision to titrate dosage to ≥90 MME/day.' **This statement does not address or suggest discontinuation of opioids already prescribed at higher dosages**, yet it has been used to justify abruptly stopping opioid prescriptions or coverage…The CDC based the recommendation on evidence of dose-dependent harms of opioids and the lack of evidence that higher dosages confer long-term benefits for pain relief. However, **we know little about the benefits and harms of reducing high dosages of opioids in patients who are physically dependent on them**."

In November 2022, the CDC issued a new clinical practice guideline for prescribing opioids for pain.[10] This revision expanded upon concerns expressed in the 2019 clarification based on growing evidence of unintended patient harm from rigid misapplication of the 2016 guideline. The revision addressed concerns related to patient abandonment – rapidly discharging a patient from care and discontinuing prescribing of opioids – as well as specific concerns related to misapplication by pharmacies.

> "Although some laws, regulations, and policies that appear to support **recommendations in the 2016 CDC Opioid Prescribing Guideline** might have had positive results for some patients, they are inconsistent with a central tenet of the guideline: that the recommendations **are voluntary and intended to be flexible to support, not supplant, individualized, patient-centered care**. Of particular concern, some policies purportedly drawn from the 2016 CDC Opioid Prescribing Guideline have been notably inconsistent with it and have gone well beyond its clinical recommendations. Such **misapplication includes** extension to patient populations not covered in the 2016 CDC Opioid Prescribing Guideline (e.g., cancer and palliative care patients), **rapid opioid tapers and abrupt discontinuation without collaboration with patients, rigid application of opioid dosage**

> **thresholds**, application of the guideline's recommendations for opioid use for pain to medications for opioid use disorder treatment (previously referred to as medication assisted treatment), **duration limits by insurers and pharmacies, and patient dismissal and abandonment**. These actions are not consistent with the 2016 CDC Opioid Prescribing Guideline and have **contributed to patient harm, including untreated and undertreated pain, serious withdrawal symptoms, worsening pain outcomes, psychological distress, overdose, and suicidal ideation and behavior**."
>
> "**This clinical practice guideline should not be applied as inflexible standards of care across patient populations by health care professionals**, health systems, **pharmacies**, third-party payers, or state, local, or federal organizations or entities."

The urgency conveyed by the 2022 revision reflects the severity of harms related to inappropriate opioid tapering and discontinuation. An analysis of Medicaid beneficiaries in Vermont from 2013–2017 found that the median length of a taper for a patient maintained on ≥120 MME for ≥90 days was one day, and that 86% were tapered in less than the recommended minimum of 21 days.[11] Half of these patients experienced an opioid-related hospitalization or emergency department visit. An analysis of Veterans Health Administration data from 2013–2014 found that stopping opioid therapy was associated with increased risk of death from overdose or suicide, and an analysis of patients enrolled in commercial insurance or Medicare Advantage from 2007–2019 found that tapering opioid dosage by ≥15% was associated with increased risk for overdose and mental health crisis.[12,13]

**D. Pharmacist Training and Practice**

The Doctor of Pharmacy (PharmD) degree is a professional doctorate. A typical PharmD program is completed over four years with the first three years occurring primarily in a classroom setting and the final year comprised of clinical experiences in a variety of healthcare settings. Since 2000, the PharmD has been the sole entry-level degree for the pharmacy profession. The Accreditation Council for Pharmacy Education (ACPE) publishes standards which outline the required elements of PharmD programs and conducts periodic evaluations to determine whether programs are meeting these standards.[14] ACPE is recognized by the U.S. Department of Education as the national agency for the accreditation of professional degree programs in pharmacy. PharmD programs generally require completion of two years of undergraduate coursework prior to entry, and some require a bachelor's degree prior to entry. The conferral of a PharmD degree signifies the recipient has demonstrated competence in the four educational domains defined by ACPE: foundational knowledge, essentials for practice and care, approach to practice and care, and personal and professional development. Competence is further demonstrated by successful completion of two standardized exams which are required for all U.S. pharmacists prior to licensure: (1) the North American Pharmacist Licensure Examination (NAPLEX) to evaluate general practice knowledge, and (2) the Multistate Pharmacy Jurisprudence Examination (MPJE) to assess application of laws and regulations. Continuing education requirements for pharmacists to maintain licensure vary by state with most states, including Georgia, requiring a minimum of 30 hours per two-year period. ACPE publishes standards which outline expectations for accredited providers, including standards for integrity and independence.[15] While some states require pharmacists to complete continuing education programs in particular subject areas, pharmacists typically maintain substantial autonomy in selecting which specific programs to complete from a broad array of accredited providers. Notably, Georgia and the Georgia Board of Pharmacy do not require the completion of continuing education in any specific topic areas.[16] I am not aware of any ACPE accredited continuing education programs that purport to educate pharmacists about "red flags" bearing substantial similarity to the 14 computations defined in the Catizone report.

In 2017, the *American Journal of Pharmaceutical Education* published an American Association of Colleges of Pharmacy committee report outlining the core entrustable professional activities (EPAs) for new pharmacy graduates.[17] According to the authors, "Core EPAs for New Pharmacy Graduates are discrete, essential activities and tasks that all new pharmacy graduates must be able to perform without direct supervision upon entering practice or postgraduate training." These EPAs reflect contemporary PharmD training and include a range of patient care and practice management activities. A growing proportion of PharmD graduates further hone these patient care skills in post-PharmD residency programs which prepare them to practice as clinical pharmacists. Clinical pharmacists typically practice in hospitals and clinics as active members of interprofessional teams, and they can be granted prescriptive authority similar to a physician assistant or advanced practice nurse.

While community pharmacists who do not complete post-PharmD residency programs are also highly trained medication experts capable of supporting optimal pharmaceutical care, a variety of logistical factors limit their ability to fully realize this potential. Two logistical limitations worthy of particular emphasis include: (1) lack of access to patients' health records, and (2) lack of timely access to prescribers for prescription clarifications. Because the indication for a medication is not a legally required element of a prescription, prescribers typically do not include it. For this reason, a pharmacist is often uncertain what condition a medication is being prescribed to treat. This problem is so pervasive that a common method of patient counseling that is taught to pharmacy students, the Indian Health Service technique, begins with the pharmacist asking the patient, "What did the doctor tell you this medication was for?"[18]

Pharmacists are trained to thoroughly evaluate the safety and efficacy of medications based on patient-specific factors, and to modify treatment plans accordingly. However, this is extremely difficult to accomplish for many conditions and medications in a community pharmacy setting because pharmacists do not have access to patients' health records. For example, the safety and efficacy of a patient's antihypertensive medication cannot be thoroughly evaluated without comprehensive consideration of prior antihypertensive medication use, current use of other medications which may interact or worsen hypertension, trends in objective data such as blood pressure and heart rate, and subjective data such as perceived symptoms and adverse effects reported during recent clinician office visits. Without this information, a pharmacist's critical evaluation of a prescription is generally limited to identifying major safety concerns, such as an excessive initial dose of an antihypertensive which could result in kidney damage. The pharmacist may be able to resolve this concern through discussion with the patient (e.g., confirms they have already been taking a lower dose of the medication obtained from another pharmacy and this is a dose increase for persistently elevated blood pressure), or they may need to contact the prescriber for clarification.

There is often a significant lag time between pharmacist outreach to a prescriber's office and receipt of a response. Based on my personal experience, at least 24–48 hours would be typical. The pharmacist is rarely able to speak with the prescriber directly, so communication is often routed through other staff in the prescriber's office.[19] In 2022, I collaborated with the American Pharmacists Association to conduct a nationwide survey of community pharmacists in which difficulty reaching prescribers was identified as one of the most significant barriers to safe and timely opioid dispensing.[20] While waiting for a prescriber's response, the pharmacist may need to exercise professional judgment in determining whether dispensing the medication or declining to dispense the medication is more likely to result in patient harm. It is often the case that either choice is reasonable and defensible. As described in the 2022 CDC revision, delays and disruptions in access to prescribed opioids can have dire consequences for people on long-term opioid therapy for chronic pain.[10]

Much as *The Hippocratic Oath* guides ethical practice for physicians, *The Oath of a Pharmacist* guides ethical practice for pharmacists.[21] Developed jointly by the American Pharmacists Association and American Association of Colleges of Pharmacy, it states:

> "I promise to devote myself to a lifetime of service to others through the profession of pharmacy. In fulfilling this vow: **I will consider the welfare of humanity and relief of suffering my primary concerns**. I will promote inclusion, embrace diversity, and advocate for justice to advance health equity. I will apply my knowledge, experience, and skills to the best of my ability to assure optimal outcomes for all patients. I will respect and protect all personal and health information entrusted to me. I will accept the responsibility to improve my professional knowledge, expertise, and self-awareness. I will hold myself and my colleagues to the highest principles of our profession's moral, ethical and legal conduct. **I will embrace and advocate changes that improve patient care**. I will utilize my knowledge, skills, experiences, and values to prepare the next generation of pharmacists. I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public."

The bolded portions of this oath demonstrate pharmacists' compassion for patients with chronic pain and help to explain why our profession joined physicians, our professional societies, and federal agencies in seeking to improve care for this population in the late 1990s and 2000s. As the unintended consequences of increased opioid prescribing became clear, our profession joined these other stakeholders in efforts to support more judicious prescribing. Now, with the unintended consequences of those supply reduction efforts becoming increasingly clear, we continue to search for an appropriately calibrated response that optimizes care for people with pain while minimizing opioid diversion and misuse.

**E. Controlled Substance Dispensing**

The United States Controlled Substances Act provides a detailed listing of required elements for a valid controlled substance prescription, including an opioid, in 21 CFR 1306. The term, "corresponding responsibility" appears specifically in 21 CFR 1306.4, which reads in its entirety:[22]

> "(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
>
> (b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.
>
> (c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.
>
> (d) A prescription may be issued by a qualifying practitioner, as defined in section 303(g)(2)G)(iii) of the Act (21 U.S.C. 823(g)(2)(G)(iii), in accordance with § 1306.05 for a Schedule III, IV, or V controlled substance for the purpose of maintenance or detoxification treatment for the purposes of administration in accordance with section 309A of the Act (21 U.S.C. 829a) and § 1306.07(f). Such prescription issued by a qualifying practitioner shall not be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients."

The actual text of 21 CFR 1306.4 describes a limited role for a pharmacist in confirming that a controlled substance prescription includes all legally required patient and prescriber data and has been issued and transmitted in a manner that minimizes risk for forgery. This is in addition to the requirement for an evaluation of the safety of the prescribed drug and dose,

to the extent possible with the limited patient data available to a community pharmacist, that is required for a prescription for a non-controlled substance.

It is notable that the Controlled Substances Act does not require a controlled substance prescription to be issued for treatment of a U.S. Food and Drug Administration (FDA) approved indication. This allows physicians and advanced practice providers to prescribe a controlled substance "off-label" – to treat a disease or symptom for which the FDA has not evaluated and confirmed the safety and efficacy of that controlled substance – just as they are allowed to prescribe non-controlled substances off-label. The ability of physicians and advanced practice providers to prescribe controlled substances off-label demonstrates the broad authority granted to them in standard medical practice and aligns with a limited role for pharmacists to interfere with access to prescribed medication only when serious safety concerns are identified.

The Catizone report notes that explicit documentation of resolving "red flags" was infrequently observed among Publix pharmacists. However, this is unsurprising given that extensive documentation of the detailed decision-making related to dispensing of any prescribed medication is extremely uncommon in pharmacy practice. For example, consider the scenario of a pharmacist who identifies a concerning drug-drug interaction. First, they will determine whether the potential drug-drug interaction that they have identified, or typically that the dispensing software has alerted them to, is truly a concern. Many drug-drug interactions that are flagged by dispensing software do not require resolution, such as two antihypertensive drugs prescribed for high blood pressure which are noted as a therapeutic duplication that increases risk for low blood pressure. In this case, the pharmacist would simply determine that no drug-drug interaction exists and continue dispensing without documenting resolution of the issue. If the pharmacist did feel a drug-drug interaction was present, they would likely communicate with the patient to determine whether they are still taking the interacting drug(s). If they are not, then they would likely determine that no drug-drug interaction exists and continue dispensing without documenting resolution of the issue. If the patient is still taking the medication, the pharmacist would likely contact the prescriber to notify them of the issue and discuss alternative treatment options. If a resolution was identified, then the pharmacist may again determine that no drug-drug interaction exists and continue dispensing without documenting resolution of the issue. In some instances, a satisfactory resolution may not be identified. The prescriber may feel strongly that the drug-drug interaction is acceptable for the patient's specific needs, and the pharmacist may or may not agree. The pharmacist would only be likely to document anything related to this scenario in the patient's record if they reached the conclusion of this example and disagreed with the prescriber enough to be concerned about the patient experiencing harm as a result of the interaction but not so concerned that they decline to dispense the medication altogether.

Despite conducting an extensive search, I was not able to identify a single research study or published report describing documentation practices by community pharmacists when

making complex dispensing decisions. Pharmacy dispensing software has not historically been designed to facilitate the documentation of patient care, and PharmD training related to documentation typically focuses on applying this skill in clinical practice environments rather than community pharmacy environments. This reflects the general disconnect between actual pharmacy practice and the assertions about appropriate controlled substance dispensing that are contained in the Catizone report. Furthermore, to my knowledge, no law, regulation, or rule in Georgia has ever included a requirement – or even encouragement – for pharmacists to document investigation or resolution of "red flags".

GA House Bill 952 was introduced in 2020 in response to policies that were implemented by Walmart which severely limited or eliminated the ability of their pharmacists to exercise professional judgment when dispensing opioids.[23] The American Medical Association issued a letter strongly supporting the bill, which had the stated goal to, "prohibit corporations that own and operate multiple pharmacies from implementing policies and procedures that restrict the quantity of controlled substances dispensed or restrict the prescriber."[24] This bill ultimately did not pass, but it was discussed during a 2020 hearing of the Georgia House of Representatives.[25] Multiple state representatives noted the state government licenses individual professionals – not corporations – to practice pharmacy. A representative from Walmart indicated that they leave ultimate decision-making authority for dispensing to their pharmacists, though this contention appeared to be inconsistent with his other statements about "centralized blocks" on prescribers. These "centralized blocks" – which are endorsed in the Catizone report – would not allow individual pharmacists to exercise their professional judgment when dispensing controlled substances. Implementing a "centralized block" for a prescriber who retains an active medical license and DEA registration to prescribe controlled substances is inappropriate and dangerous. Impacted patients may face immediate and prolonged disruption in access to legitimately prescribed controlled substances, and there is substantial risk that they will turn to an illegal market to self-treat their relevant diagnoses and prevent the severe negative symptoms of withdrawal. In June 2024, I was invited to attend the National Partner Convening for Opioid Preparedness hosted by the CDC Opioid Rapid Response Program (ORRP) in partnership with the Association of State and Territorial Health Officials. The ORRP program was developed to facilitate federal, state, and local partnership to support displaced patients receiving controlled substances when a prescriber faces punitive action from DEA or the Office of the Inspector General (OIG).[26] Multiple representatives from federal agencies and state-level partners noted that dangerous disruptions in access to controlled substances are increasingly occurring even in the absence of DEA or OIG action due to pharmacists being unable or unwilling to fill legitimate prescriptions. They were shocked to learn of the existence of these "centralized blocks", particularly given that pharmacies which have implemented them are not known to have issued any guidance to federal or state authorities for how to intervene and reach pharmacy chain decision-makers when these restrictions present an immediate threat to the health of displaced patients.

The Catizone report also describes inspections of Publix pharmacies conducted by the Georgia Drugs and Narcotics Agency (GDNA). It is notable that these inspections were described as primarily focusing on "determining a pharmacy's licensing and recordkeeping compliance", as well as evaluating cleanliness, vaccine protocols, and physical security. Board inspections play a critical role in guiding pharmacy chains in interpreting and applying state rules for pharmacy practice. Mr. Catizone contends that these inspections did not provide an appropriate level of scrutiny of controlled substance dispensing and documentation. If true, this would indicate pharmacy practice standards in the state during the relevant timeframe were not consistent with his description of those standards. However, the GDNA inspection forms and the Troughton testimony indicate that the agents did in fact spend significant time in Publix pharmacies conducting inspections and providing guidance on identifying potentially invalid controlled substance prescriptions. This is more consistent with my understanding of the approach to this issue from boards of pharmacy and related state-level regulatory bodies. The fact that these inspections did occur and Publix pharmacies were not routinely cited for their practices related to "red flag" dispensing and documentation further undercuts the opinions described in the Catizone report.

Mr. Catizone's discussion of the MPJE is also notable. Pharmacists in Georgia must pass this examination assessing application of pharmacy laws and regulations prior to obtaining licensure. Mr. Catizone specifically notes that the MPJE has included emphasis on corresponding responsibility and "red flags" since 2010. Given these facts, it would be reasonable for a pharmacy chain to trust the licensed pharmacists they employ to use their professional judgement in exercising their corresponding responsibility when dispensing controlled substances.

**F. Risk Identification Tools**

Prescription monitoring programs (PMPs) are state-level databases containing dispensing data for controlled substances which can be queried by law enforcement officials, prescribers, and pharmacists to identify aberrant patterns of prescribing, dispensing, and use. However, limited evidence is available to support their use as a patient care tool, and their development has been driven primarily by law enforcement entities.[27] Analyses of the public health impact of PMP implementation have generally shown a decrease in deaths due to opioid analgesics and a corresponding increase in deaths due to illegal opioids.[28,29] In 2021, the American Medical Association issued a report noting that opioid overdose deaths continue to rise each year to unprecedented levels despite substantial increases in prescriber use of PMPs.[30] Experts in controlled substance policy and law have described additional potential risks associated with PMPs and the predictive analytics (e.g., risk scores, "red flags") they typically feature. These risks include perpetuating bias and negative impacts on poor, immigrant, and stigmatized communities.[27] While some regulatory bodies recommend that pharmacists review PMP data prior to dispensing controlled substances, there are no established best practices for analyzing PMP data or for training pharmacists to do so. Notably, Georgia does not require that pharmacists check the PMP prior to dispensing controlled substances. Furthermore, in a 2017 communication, the Georgia Drugs and Narcotics Agency stated, "Nothing shall require a dispenser to obtain information about a patient from the PDMP, provided however, that dispensers are encouraged to obtain such information while keeping in mind that the purpose of such data base includes reducing duplicative prescribing and overprescribing of controlled substances."[31]

Dispensing "red flags" represent an even less precise option for identifying potentially illegitimate controlled substance prescriptions or predicting risk for controlled substance misuse, diversion, and harm. As demonstrated by multiple extensive and inconsistent lists of "red flags" described and referenced in the Catizone report, the identification, investigation, resolution, and documentation of each of these issues for every controlled substance prescription would be infeasible in a community pharmacy environment. It is notable that the U.S. Drug Enforcement Administration has published at least three iterations of the "Pharmacist's manual: An informational outline of the controlled substances act" and the term "red flag" never appears.[32-34] Nor is it suggested that pharmacists must document any and all "red flags" identified along with a description of all steps and conclusions reached by the pharmacist to resolve these "red flags". This manual only refers to prescription fraud indicators in a supplementary appendix titled, "Pharmacist's Guide to Prescription Fraud". Descriptions of criteria that may indicate a forged prescription are far ranging, including that the prescription, "…looks 'too good'. The prescriber's handwriting is too legible." Notably, these indicators bear little resemblance to the Red Flag Computations described in the Catizone report. This highlights the remarkable inconsistency and lack of a recognized standard for identifying "red flags".

In further demonstration of the remarkable inconsistency and lack of a recognized standard for identifying "red flags", the Catizone report refers to a 2014 video from the National Association of Boards of Pharmacy as if it were a clear and authoritative directive for pharmacists to follow when dispensing controlled substance. However, a careful review of this video demonstrates it is incredibly unclear in defining "red flags" and that it bears little resemblance to the red flags described in the Catizone report.[35] Throughout the video, only four specific "red flags" are listed and reinforced with accompanying text. These include: (1) prescriptions for same controlled substance, (2) customers presenting in groups, (3) unusual distance from pharmacy, (4) opioids + benzodiazepine + muscle relaxant. No additional specifics are provided to operationalize these vague definitions, nor does the video mention any requirement to document these or any other red flags prior to dispensing. The Catizone report also references a report issued by the National Association of Boards of Pharmacy that includes vaguely described "red flags" which do not correspond directly with the specific red flag computations in this case.[36] This report similarly does not mention any requirement related to documentation.

In contrast, in the context of this litigation, the Catizone report describes a concrete, rigid, and inflexible set of fourteen "red flags" that morph the general concepts of what a pharmacist might consider as a suspicious or potentially illegitimate prescription into detailed, specific criterion that appear nowhere in any recognized pharmaceutical literature. For example, the current list of "red flags" in the Catizone report takes the NABP's original concept that a customer who lives an unusual distance from the pharmacy where they are seeking to fill an opioid prescription is a potential "red flag" for the pharmacist to consider and distills it down to a specific computation that the pharmacist must flag a prescription for a customer whose address is 25 miles from the center of their zip code to the center of the zip code of the pharmacy. This seeks to convert what the NABP originally provided in 2014 from a general, context-driven guide to aid a pharmacist to use their professional judgment into a set of inflexible requirements that eliminate professional judgment and could result in patient harm. The Catizone report points to inconsistent "red flag" guidance from various pharmacy chains to their employed pharmacists as evidence of unique instances of failure in supervision, while in fact they represent further evidence that no concrete operational definitions have ever been defined and endorsed by an authoritative regulatory agency or professional organization. There is no credible support for Mr. Catizone's assertion that his detailed, specific, and inflexible criterion have been nationally applicable since 2006.

Indeed, for each "red flag" defined in the Catizone report, there are numerous adequate and common justifications for dispensing. Furthermore, pharmacists are health professionals, not law enforcement officers, and they do not receive training in conducting law enforcement investigations. When a pharmacist is evaluating a prescription and any potential "red flags", the decision is informed by limited data available in the PMP or obtained through communication with the patient or the prescriber. However, if the prescription in question is illegitimate because it is not being provided in the regular course of medical practice, then presumably the patient, the prescriber, or both are not reliable sources of

information. Obtaining information from other potential sources, such as staff at the prescriber's office or friends and family of the patient, is generally infeasible and in many cases would violate the privacy rights of the patient. It is notable that the Catizone report does not explore the real-world implications of the suggestion that pharmacists must identify, investigate, resolve, and document resolution of all potential "red flags" for every controlled substance prescription they receive.

**G. Red Flag Computations**

Each of the Red Flag Computations described in the Catizone report are addressed below. Detailed considerations of when dispensing under these conditions may be appropriate are provided. The frequencies of these "red flags" being associated with prescriptions dispensed by Publix pharmacies are indicated. In cases where multiple "red flags" are closely related the responses have been combined.

*1. An opioid was dispensed to a patient who traveled more than 25 miles to visit the pharmacy*
*2. An opioid was dispensed to a patient who traveled more than 25 miles to visit their prescriber*

Dispensing of opioids to patients who traveled more than 25 miles to visit the prescriber was extremely rare (2.5%). Dispensing to patients who traveled more than 25 miles to visit the pharmacy was rare (6.4%).

There does not appear to be a logical basis for the thresholds defined in these computations as 25 miles is not a recognized standard indicating that a prescription may be illegitimate. Community pharmacists often have familiarity with their patients that provides insight regarding the need to travel distances above this threshold. They are also in a position to quickly gather information from patients with whom they are not familiar that explains their need for travel.

Dispensing under these conditions would often be appropriate. The backlash to opioid prescribing and associated pressure on clinicians to avoid prescribing opioids has resulted in severely limited access for patients already maintained on chronic opioid analgesics. A 2018 study in Michigan attempted to describe the experience of an older adult with chronic pain maintained on daily opioid analgesics seeking to establish care with a new primary care provider.[37] In the scenario described, the patient was maintained on an extremely low daily dose of short-acting opioid following a motor vehicle crash in the distant past. Even given the patient's relatively low risk for misuse or addiction based on the scenario described, 41% of clinics reported they would not accept the patient solely because she takes an opioid analgesic. Some of the other clinics reported that they would accept the patient initially but discontinue opioid treatment within a few visits, and it is likely that many of the other clinics reporting they would accept the patient would have eventually done the same. These results highlight the challenges patients with chronic pain already maintained on opioids face in maintaining access to medications which they often report have a positive impact on their ability to lead an active and independent life. Furthermore, these results help to explain why a patient might need to travel a substantial distance to find a prescriber who is willing to continue providing them with this preferred treatment.

Similar barriers to access that require substantial travel can also be experienced at the pharmacy counter. In 2020, I led a study to assess the availability of buprenorphine/naloxone films in Texas community pharmacies.[38] Buprenorphine/naloxone is an extremely effective

medication for the treatment of opioid use disorder, and increasing prescribing of this medication has been a key focus of national opioid response efforts over the past decade. Buprenorphine is a partial agonist of opioid receptors, meaning that it weakly activates them to help prevent withdrawal and cravings. Naloxone is combined in each film to deter misuse given that buprenorphine can induce a weak opioid-like high when misused by opioid-naïve people. In our study, we called 800 pharmacies posing as a prospective new patient completing inpatient treatment for opioid use disorder and seeking to fill a commonly prescribed dose and quantity of buprenorphine/naloxone films. We found that only 42.2% of pharmacies were willing and able to dispense this vital medication promptly. Accessibility was particularly low in independent pharmacies at only 21.5%. We subsequently replicated this study in 10 additional states and found deficits in access to this vital medication were widespread.[39] These results demonstrated that a patient would likely need to visit multiple pharmacies before identifying one that would be willing to dispense this medication. Because buprenorphine/naloxone is a schedule III controlled substance with relatively low misuse potential, and opioid analgesics are schedule II controlled substances with higher misuse potential, it is likely that availability of opioid analgesics is even lower in community pharmacies. This further demonstrates a plausible rationale for why a patient might need to travel a substantial distance from their home to obtain opioid analgesics from a pharmacy.

*3. Patient was dispensed opioid prescriptions with overlapping days of supply that were written by two or more prescribers*
*4. Patient was dispensed opioid prescriptions with overlapping days of supply at two or more pharmacies*

Dispensing of opioid prescriptions with overlapping days of supply that were written by two or more prescribers was rare (8.5%). Dispensing of opioid prescriptions with overlapping days of supply at two or more pharmacies was extremely rare (1.5%).

Situations in which a patient may appropriately receive opioid prescriptions from multiple prescribers are common. For example, many patients receive pain treatment from primary care or specialty practices operated by multiple physicians. When the patient's usual prescriber is unavailable due to a vacation or other schedule limitation, they may receive care from a different physician. A patient may be prescribed an initial opioid analgesic by an emergency medicine physician following an injury, or by a surgeon following a procedure, and then be prescribed a different formulation by their primary care provider in a follow-up visit. Additionally, a patient may be prescribed a relatively weak or low-dose opioid analgesic for management of chronic pain by a primary care or urgent care provider, then referred to a pain specialist who prescribes a stronger formulation or converts them to a long-acting regimen.

It is also reasonable for a patient to occasionally obtain opioid prescriptions from multiple pharmacies, particularly in the context of very strict limitations on the timing of refills. Pharmacies often experience supply issues that can lead to delays in medication access and

may require a patient to obtain their medication at a different pharmacy if their timeframe for pickup is narrowed to only a few days. The methodology for the analysis of these "red flags" seems to include an overlap of even one day of supply though this would certainly not be problematic. Patients can typically obtain non-controlled substances at least five days prior to the next scheduled fill date to ensure no interruption in treatment despite life events which may limit ability to physically visit their pharmacy. While a narrower timeline may be reasonable for controlled substances, some flexibility that protects a patient's ability to lead a normal life is important. Requiring patients to always obtain their controlled substance prescription on the day their current supply will be exhausted, or even limiting to 1–2 days earlier, can be incredibly disruptive to a patient's life. This type of policing from healthcare professionals can understandably provoke a great deal of anxiety for the patient, as going even one day without medication can induce severe withdrawal symptoms for patients on chronic opioid analgesics. The Catizone report asserts that, "the overwhelming percentage (>60%) use one pharmacy as their primary source of medications." However, this statement relies upon a single study of Medicare Part D participants ≥ 65 years of age using data from 2009. Additional studies have found that multiple pharmacy use is increasing over time and is more common among younger patient populations.[40,41]

*5. Patient was dispensed an opioid, a benzodiazepine, and a muscle relaxer for overlapping days of supply*
*6. Patient was dispensed an opioid, a benzodiazepine, and a muscle relaxer on the same day and all of the prescriptions were written by the same prescriber*

Dispensing of an opioid, a benzodiazepine, and a muscle relaxer for overlapping days of supply was rare (3.9%). Dispensing of these three medication classes on the same day with all prescriptions issued by a single prescriber was extremely rare (0.7%).

The combination of an opioid analgesic, a skeletal muscle relaxant, and a benzodiazepine anxiolytic is sometimes referred to by law enforcement and their proxies as "The Holy Trinity". In the Catizone report, it is suggested that dispensing this combination is a clear sign of either maleficence or negligence by pharmacists and pharmacy organizations. However, I not aware of any state- or national-level prohibition on the prescribing or dispensing of this combination. Furthermore, multiple publications have demonstrated that concomitant prescribing of these medications remained quite common in regular medical practice as recently as 2017.[42,43] Pressure on physicians and advanced practice providers to avoid opioid dose escalation, decrease prescribed opioid dosages, or taper patients off opioids entirely may have driven an increase in concomitant prescribing of these drugs. Patients often report worsening pain and increased anxiety during opioid tapering, and skeletal muscle relaxants and benzodiazepine anxiolytics are among a relatively small number of affordable options that can be offered to these patients which have potential to resolve their symptoms.

*7. Patient was dispensed an opioid and a benzodiazepine within 30 days of one another*

*8. Patient was dispensed an opioid and a benzodiazepine on the same day, and both prescriptions were written by the same prescriber*

Dispensing an opioid and a benzodiazepine within 30 days of one another was uncommon (15.8%), and dispensing of an opioid and a benzodiazepine on the same day with both prescriptions issued by a single prescriber was rare (3.9%).

The concomitant use of opioids and benzodiazepines has been associated with an increased risk for adverse effects and there is a corresponding black box warning from the FDA. However, this combination is not considered contraindicated by the FDA and the 2016 CDC opioid guideline specifically noted there are circumstances in which prescribing both medications to a patient may be appropriate.[8] The American Society of Addiction Medicine states this combination is even allowable for some patients with opioid use disorder despite the relatively high risk for benzodiazepine misuse among this population.[44] Black box warnings are regularly encountered by pharmacists when dispensing prescription medications and can typically be viewed as a reminder for patient counseling. For example, all antidepressant medications have a black box warning related to the potential for increased suicidality, but they remain widely used in the U.S. Pharmacists routinely provide counseling on this issue to patients who are initiating antidepressants, but they do not question the appropriateness of these medications.

Computation 7 does not refer to overlapping days supply of opioids and benzodiazepines, but simply to receiving both medications within a 30-day period. Benzodiazepines are often prescribed at low doses and in small quantities to be used infrequently as rescue medications for panic attacks. Use of benzodiazepines in this manner represents a much lower risk combination with opioids compared to chronic daily use of benzodiazepines. However, Computation 7 captures all types of benzodiazepine utilization and misrepresents the frequency of potentially dangerous combination therapy. Notably, benzodiazepines and most opioids are relatively short-acting medications that do not present synergistic risks if they are administered on separate days.

*9. Patient was dispensed two short-acting (or immediate release) opioid drugs on the same day*

Dispensing of two short-acting / immediate-release opioids on the same day was extremely rare (2.2%).

In inpatient settings, it is common practice to order short-acting opioids of differing relative strengths to be taken intermittently depending on the severity of pain. This is a less standard practice in outpatient settings, though it may be reasonable in some circumstances for short periods of time.

*10. Patient was dispensed an opioid prescription of over 200 morphine milligram equivalents (MME) per day before 2018 or over 90 MME per day after 2018*

Dispensing of opioid prescriptions for over 200 MME per day before 2018 and over 90 MME per day after 2018 were rare (3.9%).

This metric exemplifies the rigid and dangerous misapplication of the 2016 CDC opioid guideline that the authors condemned in their 2019 clarification and 2022 revision.[8-10] Prior to publication of the 2016 guideline, titrating chronic opioid therapy to relatively high daily doses was common and had not been specifically discouraged by the CDC. Furthermore, the 2016 guideline recommended only that titration to high doses be "carefully considered" and refrained from making any recommendation regarding proactive tapering for patients already maintained on high doses. The proposal of this metric to evaluate a chain pharmacy's controlled substance dispensing practices would seem to imply the chain should implement "rigid application of opioid dosage thresholds" and "inflexible standards of care". However, the 2022 revision indicates actions such as these "have contributed to patient harm, including untreated and undertreated pain, serious withdrawal symptoms, worsening pain outcomes, psychological distress, overdose, and suicidal ideation and behavior".[10] This computation exemplifies the concerns that many experts – including myself – had regarding misapplication of the 2016 guideline.

*11. An opioid was dispensed to at least 4 different patients on the same day, and opioid prescriptions were for the same base drug, strength, and dosage form and were written by the same prescriber*

Dispensing of this type was extremely rare (0.7%).

While pattern prescribing has been observed among unscrupulous and predatory prescribers who faced direct consequences from the Drug Enforcement Administration and state medical boards, it is also reasonable to expect a fair amount of pattern prescribing from ethical providers who are providing legitimate prescriptions. Physicians and advanced practice providers regularly engage in pattern prescribing to facilitate efficient care provision, especially if they work in primary care and treat a broad range of conditions. For example, a primary care physician is likely to default to a specific antihypertensive drug, dose, and quantity for all patients, though they should also have 1-2 alternative options ready for patients with specific comorbidities that impact treatment selection. Consider the case of a patient with persistently high blood pressure who needs to initiate treatment with their first antihypertensive. Many physicians will default to selection of lisinopril 10mg daily #30 and instruct the patient to return in four weeks. However, if the patient is an older adult and at greater risk for a fall due to orthostatic hypotension (a rapid decrease in blood pressure upon standing), the physician might choose to start at a lower dose of 5mg daily. If the patient reports that they took a blood pressure medication briefly several years ago and experienced a dry hacking cough (a potential adverse effect of lisinopril and other angiotensin-converting enzyme inhibitors), the physician might instead select losartan 50mg daily. A similar cascade of considerations arises when a prescriber is selecting

antidepressants, antiepileptics, cholesterol lowering drugs, and many other classes of medications. In fact, it is reasonable to assume that engaging in pattern prescribing related to opioids would be even more common and appropriate because there are fewer important differentiations between opioid drugs that could be impacted by comorbidities.

*12. An opioid prescription was refilled more than 5 days before the patient's previous prescription should have run out*

Dispensing of an opioid prescription refill more than five days before the patient's previous prescription should have run out was extremely rare (0.3%).

This is appropriate given that doing so should be considered only in specific circumstances, though there are situations in which such dispensing would be acceptable. For example, a patient might lose their medication, accidentally destroy it (e.g., spill tablets/capsules into wet sink), or have it stolen. Alternatively, they might be traveling to a remote rural area with limited pharmacy access or to a country with differing opioid formulations. Additionally, if there is a dosing regimen change (e.g., increased frequency from twice daily to three times daily) then there will falsely appear to be an overlap in day of supply. Each of these situations would necessitate an early refill to avoid disruptions in pain treatment and induction of opioid withdrawal. However, the lost/destroyed/stolen explanations should not be routine and a discussion with the prescriber may be required if they occur multiple times.

*13. A patient was dispensed more than 210 "days of supply" of all opioids combined in a 6-month period*

Dispensing of more than 210 days' supply of all opioids combined in a 6-month period was uncommon (15.2%).

There is nothing concerning about dispensing of this type. Concurrent use of short- and long-acting opioids is extremely common in patients with chronic pain, so a combined days' supply of opioids ≥210 days over a period of approximately 183 days is unremarkable. Even if this metric were limited to only short-acting opioids, or only long-acting opioids, adjustments to a patients opioid dosing regimen over time could easily account for this occurrence. For example, a patient who is initiated on an opioid for acute or chronic pain may find that the dose that was initially prescribed is insufficient to alleviate their symptoms and improve physical function. This is particularly likely if the prescriber is attempting to minimize opioid use and begin with the lowest effective dose. After a period of days or weeks, they would be re-evaluated by the prescriber and instructed to increase the number of tablets they take until their supply is exhausted. The prescriber would then submit a new prescription for a higher dose or quantity, but there would appear to be an overlapping days supply. A prescriber may also decide to transition a patient from one opioid medication to another while instructing the patient to discard the remaining supply of the prior opioid medication. This would again appear to be overlapping supply according to Computation 13.

Acceptance of this "red flag" would essentially render all instances of long-term opioid therapy for chronic pain as suspicious, regardless of the underlying indication or other patient circumstances, and this is clearly inappropriate given the prevailing clinical guidance during this timeframe.

*14. A patient was dispensed an opioid and paid in cash*

Dispensing an opioid to a patient who did not use prescription insurance was uncommon (12.4%).

The origin of this "red flag" is unclear, and I am not aware of any studies demonstrating a positive association between "cash payment" and risk for misuse or diversion of opioids or other controlled substances. Furthermore, a lack of prescription insurance is likely to be influenced by a range of personal and socioeconomic factors. According to the CDC, 9.7% of all Americans and 13.9% of working-age adults were uninsured as of 2020.[45] Hispanic, Black, American Indian/Alaska Native, and Native Hawaiians and Other Pacific Islander populations are all more likely than White Americans to be uninsured.[46] Thus, subjecting customers who obtain controlled substance prescriptions without insurance to additional scrutiny would likely result in a disproportionately negative impact on these populations.

This computation does not consider whether the patient had prescription insurance coverage, and the frequency of dispensing under that condition would likely be substantially lower. Even patients who do have prescription coverage for medications may find that the cash price is lower than their copayment amount. An analysis of dispensing data from 2013 found that more than one-third of insurance copayments for hydrocodone/acetaminophen – the most commonly prescribed opioid analgesic at the time – exceeded the cash price by an average of $6.94.[47] Given this fact, it would have been reasonable for both patients and pharmacists to prefer cash payments for this medication. The same analysis found this type of overpayment was common across many frequently prescribed medications, so it is likely that it impacted other opioid analgesics throughout the timeframe of this case.

**H. Conclusion**

The basis and reasons for each of my opinions is set forth herein and are premised upon my education, training, and experience in the practice and regulation of pharmacy. My opinions are based upon a synthesis of the information reviewed, including research of the professional literature and the facts of the case and materials reviewed. When citing published studies and reports, I do not claim to endorse or agree with all findings and opinions from those references. My opinions are wholly independent of the requesting agent. I presently hold the opinions contained herein to a reasonable degree of professional pharmacy practice certainty. I have made a good faith effort to identify all my opinions related to this subject matter. However, I may hold other relevant opinions that are not expressly identified in this written report, and I reserve the right to express those opinions if asked about them. I also reserve the right to supplement, amend, correct, or otherwise change this report as new information becomes available.

**I. Reference List**

1. Phillips DM. JCAHO Pain Management Standards Are Unveiled. *JAMA*. 2000;284(4):428-429. doi:10.1001/jama.284.4.423b
2. Vital signs: overdoses of prescription opioid pain relievers---United States, 1999--2008. *MMWR Morb Mortal Wkly Rep*. Nov 4 2011;60(43):1487-92.
3. Centers for Disease Control and Prevention. 2019 Annual Surveillance Report of Drug-Related Risks and Outcomes — United States Surveillance Special Report. 2019. November 1, 2019. Accessed July 14, 2021.
4. Ciccarone D. The triple wave epidemic: Supply and demand drivers of the US opioid overdose crisis. *Int J Drug Policy*. Sep 2019;71:183-188. doi:10.1016/j.drugpo.2019.01.010
5. Zagorski CM, Myslinski JM, Hill LG. Isotonitazene as a contaminant of concern in the illegal opioid supply: A practical synthesis and cost perspective. *Int J Drug Policy*. Sep 22 2020;86:102939. doi:10.1016/j.drugpo.2020.102939
6. Ahmad FB, Cisewski JA, Rossen LM, Sutton P. Provisional drug overdose death counts. National Center for Health Statistics. Updated November 6, 2022. Accessed December 7, 2022. https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm
7. Beletsky L, Davis CS. Today's fentanyl crisis: Prohibition's Iron Law, revisited. *Int J Drug Policy*. Aug 2017;46:156-159. doi:10.1016/j.drugpo.2017.05.050
8. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain--United States, 2016. *JAMA*. Apr 19 2016;315(15):1624-45. doi:10.1001/jama.2016.1464
9. Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. *N Engl J Med*. 2019;380(24):2285-2287.
10. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. *MMWR Morb Mortal Wkly Rep*. 2022;71:1-95. doi:10.15585/mmwr.rr7103a1
11. Mark TL, Parish W. Opioid medication discontinuation and risk of adverse opioid-related health care events. *J Subst Abuse Treat*. Aug 2019;103:58-63. doi:10.1016/j.jsat.2019.05.001
12. Oliva EM, Bowe T, Manhapra A, et al. Associations between stopping prescriptions for opioids, length of opioid treatment, and overdose or suicide deaths in US veterans: observational evaluation. *BMJ*. Mar 4 2020;368:m283. doi:10.1136/bmj.m283
13. Agnoli A, Xing G, Tancredi DJ, Magnan E, Jerant A, Fenton JJ. Association of Dose Tapering With Overdose or Mental Health Crisis Among Patients Prescribed Long-term Opioids. *JAMA*. Aug 3 2021;326(5):411-419. doi:10.1001/jama.2021.11013
14. Accreditation Council for Pharmacy Education. PharmD Program Accreditation. Accessed December 7, 2022. https://www.acpe-accredit.org/pharmd-program-accreditation/
15. Accreditation Council for Pharmacy Education. Accreditation Standards for Continuing Pharmacy Education. Accessed June 19, 2024. https://www.acpe-accredit.org/continuing-education-provider-accreditation/
16. State of Georgia. Chapter 480-3 RENEWALS, INACTIVE LICENSES, AND CONTINUING EDUCATION. Accessed June 19, 2024. https://rules.sos.ga.gov/gac/480-3

17. Haines ST, Pittenger AL, Stolte SK, et al. Core Entrustable Professional Activities for New Pharmacy Graduates. *American journal of pharmaceutical education*. 2017;81(1):S2-S2. doi:10.5688/ajpe811S2
18. Lam N, Muravez SN, Boyce RW. A comparison of the Indian Health Service counseling technique with traditional, lecture-style counseling. *J Am Pharm Assoc (2003)*. Sep-Oct 2015;55(5):503-10. doi:10.1331/JAPhA.2015.14093
19. Ventricelli DJ, Mathis SM, Foster KN, Pack RP, Tudiver F, Hagemeier NE. Communication Experiences of DATA-Waivered Physicians with Community Pharmacists: A Qualitative Study. *Subst Use Misuse*. 2020;55(3):349-357. doi:10.1080/10826084.2019.1670210
20. Hill LG, Light AE, Green TC, Burns AL, Zadeh PS, Freeman PR. Perceptions, policies, and practices related to dispensing buprenorphine for opioid use disorder: A national survey of community-based pharmacists. *Journal of the American Pharmacists Association*. 2022;doi:10.1016/j.japh.2022.08.017
21. American Association of Colleges of Pharmacy. Oath of a Pharmacist. Accessed December 7, 2022. https://www.aacp.org/resource/oath-pharmacist
22. United States Controlled Substances Act, 21 CFR § 1306.04.
23. Georgia House Bill 952, (2020). https://legiscan.com/GA/bill/HB952/2019
24. American Medical Association. AMA Support for Georgia House Bill 952. 2020.
25. Georgia House of Representatives. Access to Quality Healthcare 02.28.20. 2020. https://livestream.com/accounts/25225474/events/8737124/videos/202357199
26. Centers for Disease Control and Prevention. About CDC's Opioid Rapid Response Program. Updated May 7, 2024. Accessed June 19, 2024. https://www.cdc.gov/overdose-prevention/orrp/?CDC_AAref_Val=https://www.cdc.gov/opioids/opioid-rapid-response-program.html
27. Beletsky L. Deploying Prescription Drug Monitoring to Address the Overdose Crisis: Ideology Meets Reality. *Indiana Health Law Rev*. 2018;15(2)
28. Fink DS, Schleimer JP, Sarvet A, et al. Association Between Prescription Drug Monitoring Programs and Nonfatal and Fatal Drug Overdoses: A Systematic Review. *Ann Intern Med*. Jun 5 2018;168(11):783-790. doi:10.7326/M17-3074
29. Kim B. Must-access prescription drug monitoring programs and the opioid overdose epidemic: The unintended consequences. *J Health Econ*. Jan 2021;75:102408. doi:10.1016/j.jhealeco.2020.102408
30. American Medical Association. *2022 Overdose Epidemic Report*. 2022. https://www.ama-assn.org/system/files/ama-overdose-epidemic-report.pdf
31. Georgia Drugs and Narcotics Agency. Georgia Prescription Drug Monitoring Program. Accessed June 19, 2024. https://gdna.georgia.gov/georgia-prescription-drug-monitoring-program-ga-pdmp
32. Drug Enforcement Administration. *Pharmacist's manual: An informational outline of the controlled substances act*. 2010.
33. Drug Enforcement Administration. *Pharmacist's manual: An informational outline of the controlled substances act*. 2020.

34. Drug Enforcement Administration. *Pharmacist's manual: An informational outline of the controlled substances act*. 2022.
35. National Association of Boards of Pharmacy. New Educational Video for Pharmacists Addresses Prescription Drug Abuse. Updated May 21, 2014. Accessed December 7, 2022. https://nabp.pharmacy/news/news-releases/new-educational-video-for-pharmacists-addresses-prescription-drug-abuse/
36. National Association of Boards of Pharmacy. *Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances*. 2015.
37. Lagisetty PA, Healy N, Garpestad C, Jannausch M, Tipirneni R, Bohnert ASB. Access to Primary Care Clinics for Patients With Chronic Pain Receiving Opioids. *JAMA Netw Open*. Jul 3 2019;2(7):e196928. doi:10.1001/jamanetworkopen.2019.6928
38. Hill LG, Loera LJ, Evoy KE, et al. Availability of buprenorphine/naloxone films and naloxone nasal spray in community pharmacies in Texas, USA. *Addiction*. Jun 2021;116(6):1505-1511. doi:10.1111/add.15314
39. Hill LG, Loera LJ, Torrez SB, et al. Availability of buprenorphine/naloxone films and naloxone nasal spray in community pharmacies in 11 U.S. states. *Drug and Alcohol Dependence*. 2022;doi:10.1016/j.drugalcdep.2022.109518
40. Look KA, Mott DA. Multiple pharmacy use and types of pharmacies used to obtain prescriptions. *J Am Pharm Assoc (2003)*. Nov-Dec 2013;53(6):601-10. doi:10.1331/JAPhA.2013.13040
41. Look KA. Patient characteristics associated with multiple pharmacy use in the U.S. population: Findings from the Medical Expenditure Panel Survey. *Res Social Adm Pharm*. Jul-Aug 2015;11(4):507-16. doi:10.1016/j.sapharm.2014.10.004
42. Wang Y, Delcher C, Li Y, Goldberger BA, Reisfield GM. Overlapping prescriptions of opioids, benzodiazepines, and carisoprodol: "Holy Trinity" prescribing in the state of Florida. *Drug Alcohol Depend*. Dec 1 2019;205:107693. doi:10.1016/j.drugalcdep.2019.107693
43. Soprano SE, Hennessy S, Bilker WB, Leonard CE. Assessment of Physician Prescribing of Muscle Relaxants in the United States, 2005-2016. *JAMA Netw Open*. Jun 1 2020;3(6):e207664. doi:10.1001/jamanetworkopen.2020.7664
44. The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder: 2020 Focused Update. *J Addict Med*. Mar/Apr 2020;14(2S Suppl 1):1-91. doi:10.1097/ADM.0000000000000633
45. Cha AE, Cohen RA. *Demographic variation in health insurance coverage: United States, 2020*. 2022. *National Health Statistics Reports*. https://www.cdc.gov/nchs/data/nhsr/nhsr169.pdf
46. Tolbert J, Orgera K, Damico A. Key Facts about the Uninsured Population. Kaiser Family Foundation. Updated November 6, 2020. Accessed December 7, 2022. https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/
47. Van Nuys K, Joyce G, Ribero R, Goldman DP. Frequency and Magnitude of Co-payments Exceeding Prescription Costs. *JAMA*. 2018;319(10):1045-1046.